4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Gastroenterology Regulatory Endpoints and the Advancement of Therapeutics; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research, in cosponsorship with the American College of Gastroenterology, the American Gastroenterological Association, the Crohn's and Colitis Foundation of America, Inc., the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition, the North American Society for the Study of Celiac Disease, and the Pediatric Inflammatory Bowel Disease Foundation, is announcing a 2-day public workshop entitled "Gastroenterology Regulatory Endpoints and the Advancement of Therapeutics (GREAT III)." The purpose of this workshop is to provide a forum to consider issues related to selection of endpoints and clinical outcome measures appropriate for drug development in the following disease areas: Inflammatory bowel diseases and celiac disease.

DATES: The public workshop will be held on March 30 and 31, 2015, from 8:30 a.m. to 5 p.m.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to

http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

FOR FURTHER INFORMATION CONTACT: Kelly Richards, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., rm. 5237, Silver Spring, MD 20993-0002, 240-402-4276, FAX: 301-796-9904, email: GREAT@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

This workshop will address endpoints for registration trials in inflammatory bowel diseases and celiac disease. Stakeholders, including industry sponsors, academia, patients and FDA, will address challenging issues related to selection of endpoints and assessment methodologies in clinical trials intended to support approval of products for treatment of inflammatory bowel diseases and celiac disease. The first day of the workshop will discuss the assessment of efficacy in Crohn's disease trials, including the use of patient-reported outcome measures and endoscopic evaluation, as well as the role of registries and patient participation in inflammatory bowel disease drug development programs. The second day of the workshop will discuss the appropriate target population for pharmacological therapy in celiac disease, and the definition and measurement of a treatment benefit in celiac disease registration trials, including the role and timing of assessment of histological and serological endpoints.

I. Participation in the Public Workshop

There is no fee to attend the public workshop, but attendees must register in advance. Space is limited and registration will be on a first-come, first-served basis. Persons interested in attending this workshop must register online at http://www.great3.org before March 1, 2015. For those without Internet access, please contact Kelly Richards (see FOR FURTHER INFORMATION CONTACT) to register. Onsite registration will not be available.

If you need special accommodations due to a disability, please contact Kelly Richards (see FOR FURTHER INFORMATION CONTACT) at least 7 days in advance.

II. Transcripts

Transcripts of the workshop will be available for review at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and on the Internet at http://www.regulations.gov approximately 30 days after the workshop. A transcript will also be available in either hard copy or on CD-ROM after submission of a Freedom of Information request. Send written requests to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Fax requests to 301-827-9267.

Dated: January 22, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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